

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION**

OUTSOURCING FACILITIES ASSOCIATION, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG  
ADMINISTRATION, et al.,

Defendants

and

NOVO NORDISK INC.,

Intervenor-Defendant

Case No. 4:25-cv-00174-P

**INTERVENOR-DEFENDANT NOVO NORDISK INC.'S  
OPPOSITION TO PLAINTIFFS' MOTION  
FOR A PRELIMINARY INJUNCTION AND STAY PENDING REVIEW**

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## INTRODUCTION

This case presents similar issues to those this Court addressed in *OFA v. FDA*, No. 4:24-cv-00953-P, 2025 WL 746028 (N.D. Tex. Mar. 5, 2025) (“*OFA I*”). FDA has again carefully considered data regarding the supply and demand for drugs on the shortage list—Novo Nordisk’s FDA-approved injectable semaglutide medicines, Ozempic® and Wegovy®. FDA reasonably concluded that the record as a whole supported its conclusion that the supply exceeds demand or projected demand for these drugs. That is all the Administrative Procedure Act requires.

Plaintiffs fault FDA for examining cumulative data over time, but, as in *OFA I*, that choice was FDA’s to make. Plaintiffs contend (Pls.’ Br. 7) that FDA relied on data “[REDACTED] [REDACTED],” but that assertion is unsupported *ipse dixit*. In actuality, FDA assessed all the data before it, which showed that [REDACTED] [REDACTED] [REDACTED]. Plaintiffs’ efforts to resist this reasonable conclusion rest on misstatements or misreadings of the data before the agency. Plaintiffs also purport to fault FDA for failing to consider “transitional” demand, but FDA expressly did so, reasonably concluding that Novo Nordisk’s supply more than outweighed any reasonable measure of demand or projected demand.

Plaintiffs also reassert their argument from *OFA I* that removal from the shortage list requires notice-and-comment rulemaking. It does not.

FDA reasonably determined that the shortage had resolved. There is no basis for compounders to continue compounding unsafe, knockoff versions of Novo Nordisk’s FDA-approved medicines. This Court should deny the motion for a preliminary injunction. In the alternative, with the administrative record now produced, this Court could issue a judgment on the merits in favor of Defendants pursuant to Federal Rule of Civil Procedure 65(a)(2).

## BACKGROUND

The Court’s recitation of the regulatory background in *OFA I* applies equally to this case. *See* 2025 WL 746028, at \*1–2.

Ozempic® and Wegovy® are the only two injectable semaglutide medicines approved by FDA for the U.S. market. (FDA 000004).<sup>1</sup> FDA placed Ozempic® and Wegovy® on the shortage list in 2022. (FDA 000001). Over the course of five months, from September 2024 to February 2025, Novo Nordisk made regular submissions to FDA to demonstrate that the drug shortage should be declared over. (*See, e.g.*, FDA 000051–000497). It provided regular updates on its inventory of Ozempic® and Wegovy®. (*See* FDA 000051–53 (Sept. 10, 2024); FDA 000054–59 (Sept. 18, 2024); FDA 000060–67 (Oct. 15, 2024); FDA 000214–226 (Nov. 1, 2024); FDA 000271–286 (Dec. 4, 2024); FDA 000287–304 (Dec. 19, 2024); FDA 000425–429 (Feb. 4, 2025)). It also provided detailed responses to questions that FDA posed about those reports, as well as data metrics relating to inventory, supply, and demand that FDA requested. (*See* FDA 000261–270 (Nov. 18, 2024); FDA 000357–394 (Jan. 9, 2025); FDA 000402–424 (Jan. 24, 2025); FDA 000478–497 (Feb. 13, 2025)). From this lengthy and detailed review, FDA found that Novo Nordisk had submitted “[REDACTED]”  
[REDACTED]  
[REDACTED]  
[REDACTED].” (FDA 000014).

On February 21, 2025, FDA removed Ozempic® and Wegovy® from the drug shortage list (FDA 000001–13), determining that the “demand or projected demand” for each of these medicines no longer “exceed[ed] the supply of the drug.” 21 U.S.C. § 356c(h)(2). FDA explained

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<sup>1</sup> All citations to “(FDA 000xxx)” are to the Administrative Record (ECF 49).

the bases for its decision in a 37-page Decision Memorandum. (FDA 000014–50). Three days later, on February 24, 2025, Plaintiffs Outsourcing Facilities Association (“OFA”) and Northern American Custom Laboratories, LLC (“FarmaKeio”) filed this action. Because they wish to continue selling non-FDA-approved knockoffs of Novo Nordisk’s medicines, Plaintiffs seek a preliminary injunction to force FDA to place semaglutide injection medicines back on the shortage list.

## ARGUMENT

### I. Plaintiffs Are Not Likely to Succeed on the Merits.

#### A. FDA’s decision was not arbitrary and capricious.

“Agency decisions are presumptively valid; the plaintiff bears the burden of showing otherwise.” *OFA I*, 2025 WL 746028, at \*8 (citing *Barr v. SEC*, 114 F.4th 441, 447 (5th Cir. 2024)). The arbitrary and capricious standard of review is “narrow and highly deferential.” *Sierra Club v. United States Env’t Prot. Agency*, 939 F.3d 649, 672 (5th Cir. 2019). An agency’s explanation need not “be perfect”; FDA “needed only to articulate a rational relationship between the facts found and the choice made.” *OFA I*, 2025 WL 746028, at \*11 (internal quotation marks omitted). In this case, the “question before the Court is whether the FDA’s decision, that supply of the [Novo Nordisk] drugs outpaced demand for a period of time, was reasonable in light of the evidence before it.” *Id.*

As in *OFA I*, FDA carefully considered several categories of data that persuasively demonstrated that the semaglutide injection shortage had ended. Plaintiffs’ criticisms of FDA’s decisionmaking rest on improper mathematical manipulations of the data considered by FDA and a fundamental misreading of FDA’s thorough, reasoned decision.

FDA properly focused its analysis upon the statutory definition of “shortage”—whether there was “a period of time when the demand or projected demand for the drug within the United

States exceeds the supply of the drug.” 21 U.S.C. § 356c(h)(2). Consistent with that statutory language, FDA evaluated “[REDACTED]

[REDACTED].” (FDA 000016 (emphasis added)).

To reach its “[REDACTED]  
[REDACTED],” (FDA 000018),  
FDA considered a broad array of data provided by Novo Nordisk, including [REDACTED]  
[REDACTED]  
[REDACTED]. (See FDA 000018–34). FDA also  
considered information provided by other stakeholders, including patients, healthcare providers,  
and compounders. (See FDA 000034–47). FDA considered the limitations in all of the data before  
it and how those limitations factored into its analysis and decision.

FDA did not rely exclusively upon a single data source or measure in determining whether  
nationwide supply exceeds demand, but instead holistically reviewed various metrics for  
calculating supply and demand to form a comprehensive view of a complex, nationwide market.  
Ultimately, FDA reasonably concluded that Novo Nordisk’s supply of its FDA-approved  
semaglutide injection medicines meets or exceeds demand based upon the key facts that: (1) Novo  
Nordisk was able to [REDACTED]  
[REDACTED] (FDA 000024, FDA 000044); (2) *after* fulfilling these orders, Novo  
Nordisk [REDACTED]  
[REDACTED] (FDA 000044)<sup>2</sup>; (3) Novo Nordisk expected to [REDACTED]

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[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] (FDA 000032); and (4) Novo Nordisk predicted that, even after fulfilling all anticipated orders, it would [REDACTED]  
[REDACTED]  
[REDACTED] (FDA 000034).

FDA’s assessment of demand was based on a similarly robust set of data, including—but not limited to—[REDACTED]  
[REDACTED]. (See FDA 000022, 30). FDA also relied on projected demand calculations that were based not only on “[REDACTED]” but also on “[REDACTED]  
[REDACTED],” [REDACTED]  
[REDACTED]. (FDA 000031–32). FDA recognized that Novo Nordisk’s [REDACTED]  
[REDACTED] from patients moving from non-FDA-approved compounded semaglutide drugs to Novo Nordisk’s approved medicines. (FDA 000032). Nonetheless, FDA reasonably concluded that because Novo Nordisk was already [REDACTED] and was [REDACTED]  
[REDACTED], Novo Nordisk would be able to meet demand even if—due to greater use of approved medicines as a result of compounding curtailment—it exceeded Novo Nordisk’s demand projections. (FDA 000032–33).

In reaching these conclusions, FDA properly recognized that, based on the statutory definition of “shortage,” the “[REDACTED]  
[REDACTED]  
[REDACTED].” (FDA 000041 (footnote omitted)); *see also id.* n.137). Plaintiffs claim (at 2) that FDA should have also considered demand for *compounded semaglutide* in its demand calculation. But the text and structure of the FDCA’s shortage and compounding

provisions—including the use of the definite article “the” to refer to projected demand and supply for “the drug” in question—compels the approach that FDA took. *See* 21 U.S.C. § 356c(h)(2); *see also* 21 C.F.R. §§ 314.81(b)(3)(iii)(d), (b)(3)(iii)(f) (adopting statutory definition to apply to drug shortage determination under 21 U.S.C. § 356e); *see also* Pub. L. 113-54, 127 Stat. 587 (2013) (codified at various provisions including 21 U.S.C. § 353b).

FDA also recognized—as it did in *OFA I*, *see* 2025 WL 746028, at \*14—that there would likely be *some* amount of transitional demand. In other words, FDA considered transitional demand in evaluating “[REDACTED].” (*See* FDA 000033; FDA 000042). FDA also reasonably determined that (1) it was [REDACTED], but it was unlikely to be “[REDACTED]” (FDA 000045); and (2) [REDACTED] [REDACTED] (FDA 000045–46).<sup>3</sup> As in *OFA I*, that reasoning was not arbitrary and capricious. *See* 2025 WL 746028, at \*14.

Indeed, while FDA reasonably determined that transitional demand was unlikely to be one-for-one with demand for non-FDA-approved compounded semaglutide, it also rationally concluded that Novo Nordisk’s inventory was sufficient to meet whatever levels transitional demand ultimately reach. (*See* FDA 000045–46). As Plaintiffs note (at 18), FDA had before it evidence that [REDACTED]

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<sup>3</sup> FDA thoroughly explained why predicting transitional demand would be difficult. FDA acknowledged the “[REDACTED]” in the data provided by compounders and the innate “[REDACTED].” (FDA 000033). FDA also noted that “[REDACTED]” how many patients using non-FDA approved compounded products would switch to Novo Nordisk’s approved medicines because: (1) “[REDACTED]”; (2) FDA “[REDACTED]”; (3) [REDACTED]; and (4) [REDACTED]. (FDA 000045).

██████████. It was therefore reasonable for FDA to conclude, given that Novo Nordisk ██████████  
██████████  
██████████, that it ██████████  
██████████. (See FDA 000044–46).

Thus, FDA rationally concluded that this data “██████████  
██████████.” (FDA 000022). That  
conclusion constitutes a “rational connection between the facts found and the choice made.”  
*Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962).

**B. Plaintiffs’ criticisms are misplaced.**

Plaintiffs make four arguments that FDA’s decision was arbitrary and capricious. (See Pls.’  
Br. 6–18). None supports such a finding.

**1. FDA reasonably relied on Novo Nordisk’s robust demand data.**

Plaintiffs argue (at 7–8) that Novo Nordisk’s demand data “██████████  
██████████.” Specifically, Plaintiffs argue that FDA’s consideration of ██████████  
██████████  
██████████  
██████████

To begin, ██████████ filled *would* approximate demand in the  
absence of a shortage. Plaintiffs’ view that these metrics cannot accurately measure demand simply  
assumes their preferred conclusion—*i.e.*, that a shortage exists. Of course, data on ██████████  
██████████ cannot—standing alone—determine whether there is a shortage. But that is  
why FDA relied on a broad range of data in reaching its reasoned conclusion that supply exceeded  
demand.

Furthermore, FDA recognized that all purported measurements of demand will have limitations. (*See, e.g.*, FDA 000030 (“[REDACTED]” and “[REDACTED]”). Accordingly, FDA did not rely exclusively on [REDACTED] when determining whether demand exceeded supply. It also did not rely on these data in isolation. Rather, FDA reasonably evaluated these measures in the broader context of available product throughout the supply chain.

FDA also placed weight on the fact that [REDACTED]

[REDACTED]. (FDA 000028). In fact, between October–December 2024, [REDACTED]

[REDACTED] (*See* FDA 000029 (Tbl. 6)).

Finally, FDA did not consider [REDACTED] in a vacuum. Instead, FDA looked [REDACTED]

[REDACTED]. (FDA 000029–31). [REDACTED] “[REDACTED]

[REDACTED].” (FDA 000030 (internal quotation marks and footnote omitted)). Instead, as FDA reasonably noted, [REDACTED] can be due to a number of other factors that have nothing to do with [REDACTED]

[REDACTED]. (*See* FDA 000039).

Rather than “[REDACTED]” the possibility of a shortage, FDA employed a reasonable methodological approach to Novo Nordisk’s actual demand data. And, as already discussed, FDA’s approach to projected demand—including its determination that Novo Nordisk had sufficient supply to accommodate any transitional demand—was reasonable. *See supra* section I.A. There is no basis to disturb its conclusion. *See, e.g., FCC v. Prometheus Radio Project*, 592 U.S. 414, 425 (2021) (agency decision was not arbitrary and capricious when agency explained how it factored data limitations into its analysis).

**2. Novo Nordisk’s data was not deficient and demonstrated that supply exceeded demand.**

After contending (incorrectly) that Novo Nordisk’s data excludes the possibility of a shortage, Plaintiffs about-face and assert (at 9–13) that Novo Nordisk’s data *confirms* that there was a shortage. This argument is also incorrect.

Plaintiffs maintain that Novo Nordisk’s data reveals a [REDACTED]. To make that claim, Plaintiffs generate tables of their own (at 9–10) that misread or misstate the actual data, resulting in apples-to-oranges comparisons and inaccurate conclusions.

To begin, Plaintiffs assume without any basis (at 10) that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] As explained above, Novo Nordisk has [REDACTED]

[REDACTED]. *See* Part I.A, *supra*. [REDACTED]

[REDACTED]

[REDACTED].

Accordingly, what Plaintiffs’ tables label as “Supply”—the “[REDACTED]”  
[REDACTED]”—reflect only a portion of total supply.<sup>4</sup> (*See* Pls.’ Br. 9 n.6, 10). That is why [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]. (*See* FDA 000027–28). And, as this Court has recognized, it was not arbitrary and  
capricious for FDA to consider cumulative data. *See OFA I*, 2025 WL 746028, at \*11.<sup>5</sup>

Plaintiffs argue that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. This reveals the innate flaw in Plaintiffs’ logic—in a functioning supply chain, product is constantly changing hands. Accordingly, a snapshot in time of supply can change in minutes when an in-transit truck drops off product at the warehouse or another wholesaler places an order. Given this, FDA’s choice to look at supply as [REDACTED]

[REDACTED] was reasonable. This Court’s reasoning in *OFA I* equally applies: “It is axiomatic that to consider something for a period of time”—in this case, [REDACTED]

<sup>4</sup> By contrast, FDA looked to the “ [REDACTED] ” (Tables 4 and 5) in the narrower context of comparing this “ [REDACTED] ” [REDACTED]. (FDA 000025–26).

<sup>5</sup> Plaintiffs' comparison of [REDACTED] from Tables 4 and 5 with Figures 1 and 2 results in an apples-to-oranges comparison. The purported discrepancies reflected in Plaintiffs' newly generated tables (Pls.' Br. at 9–10) are nothing more than the result of their improper combination of [REDACTED] (Tables 4 & 5) with [REDACTED] (Figures 1 & 2) metrics. (*See* FDA 000422 n.6).

██████—“requires considering it for the entire period of time.” *OFA I*, 2025 WL 746028, at \*11. It is irrelevant whether “there were data points from shorter periods of time, within the overall time frame, that could lead to a different result.” *Id.*

Plaintiffs also complain that [REDACTED]. [REDACTED]. (*See* Pls.’ Br. 11–13). But FDA expressly considered that issue in detail. FDA credited Novo Nordisk’s explanation that [REDACTED]. (*See* FDA 000023–25). This conclusion was reasonable based upon the data FDA had before it. [REDACTED]

[REDACTED]. (See FDA 000026 (Tbl. 5)). This data further supports FDA's [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] (FDA 000023–

24).<sup>6</sup> Crucially, FDA noted that [REDACTED]

[REDACTED]

[REDACTED]. (FDA 000029 (Tbl. 6)). [REDACTED]

[REDACTED]. FDA therefore

reasonably credited the conclusion that [REDACTED]

[REDACTED] (FDA 000023–25).

<sup>6</sup> As Novo Nordisk explained: “[REDACTED]”  
[REDACTED]  
[REDACTED]” (FDA 000414).  
[REDACTED]  
[REDACTED]” (*Id.*).

Plaintiffs (at 13) question why [REDACTED]  
[REDACTED]. But plaintiffs ignore Novo Nordisk’s business interest in smoothing supply on a *nationwide* basis in order to minimize *localized* supply chain disruptions. As Novo Nordisk explained to FDA, it had previously [REDACTED]  
[REDACTED]  
[REDACTED].” (FDA 000387). To address this logistical issue—which could result in frustrated customers and long-term drop in demand—[REDACTED]  
[REDACTED].” (FDA 000413 (emphasis added)). Plaintiffs’ argument also fails to account for the fact that Novo Nordisk’s medicines were approved by FDA to treat chronic conditions, often requiring long-term if not lifetime use. (*See* FDA 000004). Beyond Novo Nordisk’s commitment to “[REDACTED]  
[REDACTED]” (FDA 000366), any rational economic actor would have an interest in ensuring that customers are able to use its products for more than just [REDACTED]. That is why Novo Nordisk, as explained to FDA,  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]. (FDA 000414–415).

All of this is consistent with a critical fact: As FDA correctly observed, Novo Nordisk had [REDACTED]. (*See* FDA 000024). In trying to undermine this conclusion, Plaintiffs improperly compare [REDACTED]  
[REDACTED]  
[REDACTED]. (Pls.’ Br. 13–14). [REDACTED]

[REDACTED]. (See FDA 000019 ([REDACTED]  
[REDACTED] “ [REDACTED]  
[REDACTED] ”)). [REDACTED]  
[REDACTED]  
[REDACTED].

As FDA recognized, when looked at the right way, the [REDACTED] demonstrated that  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]. (FDA 000026 (Tbl. 5)). [REDACTED]  
[REDACTED]. (FDA  
000020 (Tbl. 2)). This demonstrates the reasonableness of FDA’s conclusion [REDACTED]  
[REDACTED] “ [REDACTED] ” that “ [REDACTED]  
[REDACTED]. ” (FDA 000024).

In all events, the fact that Novo Nordisk [REDACTED]  
[REDACTED] for the reasons described above cannot be a reason  
that FDA’s conclusion that the shortage had ended as of *February 2025* was arbitrary and  
capricious. There is no dispute that [REDACTED]  
[REDACTED]. (FDA 000025–26; see FDA 000019 n.20 (explaining that “ [REDACTED]  
[REDACTED]  
[REDACTED] ”)). The most recent data *was* the most relevant because a decision “based on  
data that is more than a month old cannot be said to be based on ‘the latest information’ available.”  
*OFA I*, 2025 WL 746028, at \*5.

**3. FDA did not err in considering Novo Nordisk’s inventory reports.**

Plaintiffs also criticize FDA’s consideration of Novo Nordisk’s inventory reports, asserting (at 14) that “[REDACTED]” But FDA explained that “[REDACTED]”

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].” (FDA 000019 (footnote omitted)). [REDACTED]

[REDACTED]

[REDACTED]. (Pls.’ Br. 14 (citing FDA 000019–20)).

Plaintiffs contend (at 14) that [REDACTED]

[REDACTED]. But this fundamentally misconstrues how [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. (See FDA 000020 (Tbl. 1) ([REDACTED])). To then determine [REDACTED]

[REDACTED]

[REDACTED] Hence, [REDACTED]

[REDACTED].

Plaintiffs also say (at 15–16) that FDA [REDACTED]

[REDACTED]

[REDACTED]. The record reveals—and FDA acknowledges—that “[REDACTED]

[REDACTED]” to be nothing more than a scrivener’s error. [REDACTED]

[REDACTED]  
 [REDACTED]  
 [REDACTED]. (*Compare* FDA 000022 (Tbl. 3), *with* FDA 000067 (Week of [REDACTED] data), *and* FDA 000226 (Week of [REDACTED] data)). And in any event, FDA relied on Table 3 for the unrelated (and correct) fact that [REDACTED]  
 [REDACTED]—including “[REDACTED]  
 [REDACTED]  
 [REDACTED].” (FDA 000021).

**4. FDA properly discounted unreliable submissions from compounders.**

Plaintiffs rehash (at 16–18) their complaint from *OFA I* that FDA credited comprehensive manufacturer data over decontextualized screenshots of pharmacy ordering portals. This Court’s conclusion that FDA’s consideration of wholesaler website screenshots was not arbitrary and capricious applies equally to this case. *See OFA I*, 2025 WL 746028, at \*12 (“[T]he Court finds that the FDA’s review and explanation of the data related to screenshots of wholesalers’ websites was not unreasonable in light of the additional data provided and supply chain dynamics.”); *id.* (“Given the issues with the evidence as articulated by the FDA, the Court finds that the FDA did not unreasonably determine that Lilly’s evidence is not outweighed by the patient survey reports.”); *id.* at \*13 (“The Court finds that it was not unreasonable for the FDA to give more weight to the specific, reliable, comprehensive and current information from Lilly, than the news reports and blog posts from sources who may have had ulterior motives and lacked the same detailed data presented to the FDA.”).

It was again reasonable for FDA to conclude that screenshots showing one individual compounder’s experience with one wholesaler at a single moment in time captures only a discrete moment in a complex supply chain. (*See* FDA 000039–40). After all, wholesalers may refuse to

sell to individual compounders who have not previously purchased a given medicine. (*See* FDA 000039). Or wholesalers may sell small amounts at a given time due to limitations on refrigerated storage rather than product unavailability. (*Id.*) Any of these circumstances may appear as a limitation on available product in a pharmacy ordering portal. FDA’s corresponding explanation that the screenshots show that “[REDACTED]” follows logically from the nature of compounders’ evidence. (*Id.*)

Given these limitations, FDA reasonably concluded that the website screenshots did not outweigh the comprehensive data provided by Novo Nordisk that demonstrated that it was meeting or exceeding demand. (FDA 000039–40). The data showed what screenshots could not: [REDACTED]. (*See* FDA 000028–29).

**C. Plaintiffs’ notice-and-comment claim is not likely to succeed.**

According to Plaintiffs, FDA’s determination that the U.S. supply of semaglutide injection exceeds demand was a “substantive rule” subject to notice-and-comment under the APA. (Pls.’ Br. 18–24). But this Court correctly held that when FDA determines that a particular drug is not in shortage, that determination is “an informal adjudication—not a rule.” *OFA I*, 2025 WL 746028, at \*8. Plaintiffs offer no new reason to change course; instead, Plaintiffs concede that they are just preserving this argument for appeal. (Pls.’ Br. 18).

When a statute does not mandate either rulemaking or adjudication, the choice of procedure “lies primarily in the informed discretion of the administrative agency.” *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). Applying *Chenery*, the Fifth Circuit has observed that there is no “bright line distinction between rulemaking and adjudication” and that even a prospective “legal rule” can be “properly established through adjudication.” *McDonald v. Watt*, 653 F.2d 1035, 1041–42 (5th

Cir. 1981). An agency’s choice of procedures is thus “entitled to great weight” and reviewed only for “abuse of discretion.” *N.L.R.B. v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 294 (1974).

The FDCA does not require FDA to proceed by rulemaking when determining whether a shortage exists. 21 U.S.C. § 356e. So, it was entitled to exercise discretion. *OFA I*, 2025 WL 746028, at \*4–5. FDA did not abuse that discretion in proceeding by adjudication; on the contrary, the agency had sound reasons to prefer adjudication. *First*, as this Court has observed, *id.* at \*5, the FDCA requires FDA to maintain a shortage list that is “up-to-date.” 21 U.S.C. § 356e(a). But notice-and-comment rulemaking is time-consuming, involving preparation of a detailed notice of proposed rulemaking, 5 U.S.C. § 553(b), typically at least 30 days of public comment, *id.* §§ 553(c)–(d), and incorporation of potentially substantial public input into a final rule, *id.* § 553(c). Requiring FDA to declare and resolve drug shortages by notice-and-comment rulemaking would impede the statute’s textual command for timeliness. *Second*, the FDCA and its implementing regulations prohibit FDA from disclosing the most important data for a shortage determination—the manufacturer’s confidential business information. 21 U.S.C. §§ 331(j), 356e(c)(2); 21 C.F.R. § 314.81(b)(2)(vii)(b); *see also* 5 U.S.C. § 552(b)(4) (no APA exception). Thus, rulemaking would not enable FDA to disclose and solicit meaningful comment on the central basis for its proposed determination. *See OFA I*, 2025 WL 746028, at \*4 n.3.

Plaintiffs argue that FDA’s resolution of the semaglutide shortage “bears all the hallmarks of rulemaking, not adjudication.” (Pls.’ Br. 19 (cleaned up)). But a one-off shortage determination is not somehow in effect a substantive rule. And the “hallmarks of rulemaking” that Plaintiffs identify either misdescribe FDA’s fact-bound, situational determination, are fully compatible with adjudication, or both.

Rather than “promulgate a new policy-type rule or standard that will govern the FDA’s future actions,” *OFA I*, 2025 WL 746028, at \*8, the shortage resolution applies the existing definition of shortage, *see* 21 C.F.R. § 314.81(b)(3)(iii)(d)(1), to the facts before the agency. Plaintiffs’ flyspecking of Novo Nordisk’s data only underscores the function of FDA’s order: “adjudicat[ing] disputed facts in [a] particular case[.]” *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 245 (1973). This required a data-driven determination that “Novo Nordisk’s supply is currently meeting or exceeding demand for its semaglutide injection products.” (App. 064).<sup>7</sup> FDA’s order also has “immediate legal consequences for specific parties.” *OFA I*, 2025 WL 746028, at \*7. When FDA removed semaglutide injection from the shortage list, the corresponding FDCA prohibitions on compounding, 21 U.S.C. § 353b(a)(2)(A)(ii), resumed effect. That is why FDA’s discussion of the “[REDACTED]” of compounding is only about enforcement discretion. (FDA 000047).

Plaintiffs’ contention that because FDA’s determination lacked “parties,” it could not be an adjudication conflicts with binding caselaw. “[A]n agency need not be presented with a specific dispute between two parties in order to use § 554(e)’s declaratory ruling mechanism, because § 554 does not limit an agency’s use of declaratory rulings to terminating controversies between parties.” *City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012), *aff’d*, 569 U.S. 290 (2013). Plaintiffs also assume incorrectly that any order that makes new law or has prospective effect must undergo notice-and-comment. The Fifth Circuit says otherwise. *McDonald*, 653 F.2d at 1041 (prospective “legal rule” was “properly established through adjudication” without notice-and-comment). And Plaintiffs wrongly suggest that “listing decisions” are invariably substantive rules. (Pls.’ Br. 19). The precedents that Plaintiffs cite placed no weight on the presence of a list; instead, those cases addressed the same factors that confirm FDA properly proceeded by adjudication.

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<sup>7</sup> Citations to “(App. 00x)” are to Plaintiffs’ Appendix (ECF 39).

Separately, Plaintiffs cannot show prejudice required for their notice-and-comment argument. *See, e.g., City of Arlington*, 668 F.3d at 244. Plaintiffs resist that burden (at 23), but the APA mandates that “due account shall be taken of the rule of prejudicial error.” 5 U.S.C. § 706(2). And the Supreme Court has recently rejected an overly narrow construction of the harmless error rule in APA cases. *FDA v. Wages and White Lion Inves. LLC*, No. 23-1038, 2025 WL 978101, at \*24–25 (U.S. Apr. 2, 2025). Under that rule, Plaintiffs’ speculation that they allegedly incurred prejudice does not meet their burden. *See City of Arlington*, 668 F.3d at 244 (challenger’s burden to show prejudice). Plaintiffs say that FDA would have received additional data indicating a shortage via notice-and-comment. (Pls.’ Br. 23). But Plaintiffs do not furnish any data that FDA failed to consider; instead, they offer misleading manipulations of the data Novo Nordisk presented. *See United States v. Johnson*, 632 F.3d 912, 932 (5th Cir. 2011) (no prejudice from lack of notice-and-comment because petitioner did not show he “would have presented an argument the [agency] did not consider”). Plaintiffs also say that they would have discovered what “metrics the agency was relying on.” (Pls.’ Br. 23). But Novo Nordisk’s data were confidential. 5 U.S.C. § 552(b)(4). And while Plaintiffs say (at 23) that they would have had notice of “the idiosyncratic standards” to which FDA held compounders’ evidence, a “general” notice of proposed rulemaking is not required to predict the shortcomings in yet-to-be-submitted data. *See* 5 U.S.C. § 553(b).

Finally, Plaintiffs’ notice-and-comment argument is a Catch-22. Under the APA, “agencies [must] use the same procedures when they amend or repeal a rule as they used to issue the rule in the first instance.” *Perez v. Mortgage Bankers Ass’n*, 575 U.S. 92, 101 (2015). If Plaintiffs are correct that FDA must adjudicate whether a drug shortage exists through notice-and-comment rulemaking, then FDA’s placement of semaglutide injection on the shortage list in the first place was also unlawful. *See OFA I*, 2025 WL 746208, at \*6.

## II. Plaintiffs Have Not Shown Irreparable Harm.

A plaintiff must show that “*he* is likely to suffer irreparable harm.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (emphasis added)); *see also CMM Cable Rep., Inc. v. Ocean Coast Props., Inc.*, 48 F.3d 618, 622 (1st Cir. 1995) (“[T]he issuance of a preliminary injunction requires a showing of irreparable harm to the movant rather than to one or more third parties.”). Plaintiffs have not clearly shown that they are “likely to suffer irreparable harm in the absence of preliminary relief.” *Winter*, 555 U.S. at 20 (2008). Indeed, they have not even shown they will suffer an “injury in fact” and therefore lack standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *see also Barber v. Bryant*, 860 F.3d 345, 352 (5th Cir. 2017) (at the preliminary injunction stage, “plaintiffs must make a ‘clear showing’ that they have standing”).

Plaintiffs’ standing to pursue preliminary relief depends on two named plaintiffs—OFA and Farmakeio. *See Town of Chester v. Laroe Ests., Inc.*, 581 U.S. 433, 439 (2017) (“At least one plaintiff must have standing to seek each form of relief requested.”). OFA “is a trade association ... that represents outsourcing facilities.” (Compl. ¶ 4). Plaintiffs’ motion and affidavits do not describe any injury to OFA itself. So, OFA has not shown “organizational standing” to sue in its own right. *See Ass’n of Cmty. Orgs. for Reform Now v. Fowler*, 178 F.3d 350, 356 (5th Cir. 1999). Nor has OFA shown associational standing to sue on behalf of its members, which requires “specific allegations establishing that at least one *identified member* had suffered or would suffer harm.” *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009) (emphasis added).

Plaintiff Farmakeio says that it operates two compounding pharmacies under 21 U.S.C. § 353a. (App. 001). While Farmakeio asserts that it “will suffer approximately \$2,500,000 to 2,900,000 in lost revenue per month as a consequence of the FDA’s Delisting Action” (App. 003), that injury is neither a consequence of, nor redressable by, the requested injunction. By its plain language, Section 353a does not permit any additional compounding of drugs on the shortage list.

The status of FDA-approved injectable semaglutide medicines on the shortage list is therefore immaterial to Farmakeio’s ability to lawfully compound semaglutide.

Plaintiffs say (at 3) that Section 353a compounding “pharmacies ... may copy [brand-name] drugs ... during a shortage,” but nothing in Section 353a refers directly to the FDCA’s drug shortage provision, Section 356e. Instead, Plaintiffs’ standing theory relies on interpreting a provision of the FDCA—21 U.S.C. § 353a(b)(1)(D)—that generally prohibits these pharmacies from compounding “regularly or in inordinate amounts ... drug products that are essentially copies of a commercially available drug product.” Plaintiffs cling to the atextual view, endorsed by FDA guidance, that a drug product is not “commercially available” if it is in shortage.<sup>8</sup> That view contradicts the statutory language. “Commercially available” means “able to be bought or sold,” which Novo Nordisk’s FDA-approved semaglutide medicines, sold by the millions, plainly are.<sup>9</sup> Congress could not have intended to refer to the drug shortage list when it employed the statutory term “commercially available”—that list did not yet exist when Congress enacted Section 353a(b)(1)(D).<sup>10</sup> If Congress later intended to authorize Section 353a pharmacies to do additional compounding during a drug shortage, it would have said so, as it did in Section 353b. *See* 21 U.S.C. § 353b(a)(2)(A)(ii) (authorizing outsourcing facilities to compound a drug that “appears on the drug shortage list ... at the time of compounding, distribution, and dispensing”).

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<sup>8</sup> FDA, *Compounding When Drugs Are on FDA’s Drug Shortages List* (Dec. 18, 2024), <https://www.fda.gov/drugs/human-drug-compounding/compounding-when-drugs-are-fdas-drug-shortages-list>.

<sup>9</sup> “Commercially Available,” *Cambridge English Dictionary*, <https://dictionary.cambridge.org/dictionary/english/commercially-available>; *see also* *N.B. Indus. Inc. v. Wells Fargo & Co.*, 465 F. App’x. 640, 642 (9th Cir. 2012) (“To be commercially available ... a good or service must be available to be bought or sold.”).

<sup>10</sup> *Compare* Food and Drug Administration Modernization Act of 1997, Pub L. 105-115, 111 Stat. 2296, 2329 (adopting § 353a copies restriction) *with* Food and Drug Administration Safety and Innovation Act, Pub. L. 112-144, 126 Stat. 993, 1104 (2012) (creating drug shortages list).

### III. The Remaining Factors Weigh Against Injunctive Relief.

In *OFA I*, this Court concluded that the remaining factors “merge when the Government is the opposing party,” and that these factors “are a wash and do not weigh in favor of or against granting of an injunction.” 2025 WL 746028, at \*15 (internal quotation marks omitted). Accordingly, the arguments of amicus NP2Go are misplaced.

NP2Go also ignores the recognized dangers inherent in compounding drugs that are not approved by FDA—and in particular the dangers associated with compounding semaglutide injections. (NP2Go Amicus Br. (ECF 48) 6–9). FDA has warned that compounded semaglutide drugs can be “risky for patients” because they do not “undergo FDA’s review for safety, effectiveness, and quality before they are marketed.”<sup>11</sup> FDA also has alerted patients and providers to “overdoses due to dosing errors associated with compounded semaglutide”; and warned that compounders make many untested alterations—adding unstudied active ingredients, altering doses, contriving new delivery mechanisms, and even introducing unstudied salt forms of semaglutide.<sup>12</sup>

In addition, and contrary to NP2Go’s assertion (at 8), FDA has not determined that compounded semaglutide products are safe or effective. Instead, researchers analyzing compounded semaglutide have observed impurities in ingredients, including an ingredient banned by FDA for use in compounding, that are likely to expose patients to health risks. (See FDA000311–334 at Fig. 5C). Researchers have also observed differing pH levels and trace metals

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<sup>11</sup> FDA, *FDA’s Concerns with Unapproved GLP-1 Drugs Used for Weight Loss* (updated Mar. 17, 2025) <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss>.

<sup>12</sup> FDA, *FDA alerts health care providers, compounders and patients of dosing errors associated with compounded injectable semaglutide products* (July 26, 2024), <https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded>.

in compounded semaglutide products. (*See* FDA 000134). All of these changes pose safety or efficacy risks. Indeed, the use of compounded semaglutide products has been described as “the largest uncontrolled, unconsented human experiment of our lifetime.”<sup>13</sup> Recognizing this, a bipartisan coalition of thirty-eight state Attorneys General has called on FDA to take swift action against compounding pharmacies that “cut corners in pursuit of a quick profit” by selling knockoff drugs that could lead to “serious public health issues.”<sup>14</sup> Therefore, while “access to medical treatments is unquestionably in the public interest,” (Pls.’ Br. 25), “the public interest is disserved by a drug that does not afford adequate protections to its users.” *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 253 (5th Cir. 2023), *overruled on other grounds*, 602 U.S. 367, 397 (2024).

Finally, if the shortage were to go back into effect, it would “

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\_\_\_\_\_.” (FDA 000481). As Novo Nordisk told FDA as recently as \_\_\_\_\_

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<sup>13</sup> Sam Koppelman, et al., *Hims & Hers Selling GLP-1 Injection That’s Not FDA Approved, From Shady Supplies—And Won’t Make You Talk to a Doctor to Get It*, HUNTERBROOK (June 27, 2024), <https://hntrbrk.com/hims/>.

<sup>14</sup> National Association of Attorneys General, GLP-1 Drugs (Feb. 19, 2025), <https://www.naag.org/wp-content/uploads/2025/02/FDA-GLP-1-Ltrhead-e.pdf>.

## CONCLUSION

As in *OFA I*, “FDA’s decision that supply of the [Novo Nordisk] drugs outpaced demand for a period of time was reasonable in light of the evidence before it.” 2025 WL 746028, at \*11.

This Court should deny the motion for a preliminary injunction.

Respectfully submitted,

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April 10, 2025

**CERTIFICATE OF SERVICE**

I hereby certify that, on April 10, 2025, I caused the foregoing document to be filed with the Clerk of the Court of the United States District Court for the Northern District of Texas using the Court's CM/ECF system.

/s/ Trevor Carolan  
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